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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/830,189	04/21/2004	Brian S. Kelleher	028US2	7725

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EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	**PAPER NUMBER**
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/830,189	KELLEHER ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-10 and 14-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-10 and 14-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 April 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the instrument inserted through the cannula extending toward the bone, as claimed in Claims 2, 29 and 46, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-6, 8-10, and 14-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1, 14, 27, 28, 43, 44 and 60 disclose the onset EMG value is determined when an EMG signal has an amplitude greater than a predetermined (positive) value, and the predetermined value is selected from a range of 60 mv-80 mV. The current specification fails to clearly disclose the necessity of the range of 60 mV to 80 mV as the predetermined value. Resting potential of the membrane is normally in the range of -60 mV to -80 mV. A predetermined value (threshold) in the range of 60-80 mV would yield the zero potential of the axon. The current specification fails to disclose if the predetermined value of 60 mV to 80 mV is a value different from the zero potential of the axon (for instance a value of the positive potential), or if the 60 mV to 80 mV range is in fact the zero potential of the axon. If the 60 mV to 80 mV range is the positive potential, the disclosed range in both the claim and specification is a physical impossibility. The positive potential (at the peak) of an axon is in the range of 20-50 mV, which would yield a peak-to-peak value of 80-130 mV. For the purposes of examination, the Examiner is interpreting the claimed predetermined value of a positive range of 60-

80 mV to mean the “predetermined value" is nothing more than 0 mV of the action potential.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2, 29 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims disclose “at least one of” an instrument inserted through a cannula extending toward the bone. The claim language "at least one of" is used in claims to mean more than one option is being offered to perform a specific function. However, the current claim language only offers a single option, and therefore renders the claims indefinite.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 3-6, 8-10, 14, 18-28, 30-45, 47-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558) in view of Calancie et al (Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation), in view of Raymond et al (5,284,153), in view of Katims (5,806,522).

Neubardt discloses a method for spinal screw insertion and further discloses applying an electrical stimulus to the first aspect of the bone; the electrical stimulus is emitted from an electrode disposed on the distal end of at least one of a probe and surgical tool; applying an electrical stimulus comprises applying a plurality of electrical stimulus pulses; the spinal nerve exits from successive vertebrae within the patient's spine; the first aspect of the bone comprises a region within a pedicle in contact with a pedicle screw; and applying an electrical stimulus to the first aspect of the bone comprises applying the electrical stimulus to a proximal end of a bone screw inserted into the first aspect of the bone. See Figures 3 and 4; and Column 8, lines 59-67.

Neubardt however fails to disclose electrically monitoring a plurality of leg muscle myotome locations via a plurality of EMG sensors, at least one of the leg muscle myotome locations being associated with the spinal nerve; automatically determining an onset neuro-muscular response to the application of the electrical stimulus to the first aspect of the bone by automatically increasing the electrical stimulus until the onset neuro-muscular response is detected by the EMG sensors outputting a signal having an amplitude greater than a predetermined value; communicating to a surgeon operating on the patient's spine an onset electrical stimulus level which causes the onset neuro-muscular response; the plurality of electrical stimulus pulses comprises current pulses that increase over time; the plurality of electrical stimulus pulses comprises current pulses that vary incrementally; the plurality of electrical stimulus pulses comprises current pulses varied incrementally within a range from 0.5 to 32.0 milliamps; the onset neuro-muscular response is an electromyography response from a muscle coupled to

the spinal nerve; electrically monitoring the muscle myotome is performed through the use of a needle electrodes electrically coupled to the muscle myotome; the muscle myotome is disposed in one of the patient's legs; the onset neuro-muscular response is determined by assessing whether the neuro-muscular response is greater than a predetermined onset level and increasing the electrical stimulus until the determined neuro-muscular response is greater than the predetermined onset level; and the amplitude greater than the predetermined value comprises a peak-to-peak value greater than the predetermined value.

Calancie et al disclose a means for determining the evoked EMG during spinal fusion surgery and further disclose electrically monitoring a plurality of leg muscle myotome locations via a plurality of EMG sensors, at least one of the leg muscle myotome locations being associated with the spinal nerve; automatically determining an onset neuro-muscular response to the application of the electrical stimulus to the first aspect of the bone by automatically increasing the electrical stimulus until the onset neuro-muscular response is detected by the EMG sensors outputting a signal having an amplitude greater than a predetermined value; communicating to a surgeon operating on the patient's spine an onset electrical stimulus level which causes the onset neuro-muscular response; the plurality of electrical stimulus pulses comprises current pulses that increase over time; the plurality of electrical stimulus pulses comprises current pulses that vary incrementally; the plurality of electrical stimulus pulses comprises current pulses varied incrementally within a range from 0.5 to 32.0 milliamps; the onset neuro-muscular response is an electromyography response from a muscle coupled to

the spinal nerve; electrically monitoring the muscle myotome is performed through the use of a needle electrodes electrically coupled to the muscle myotome; the muscle myotome is disposed in one of the patient's legs; the onset neuro-muscular response is determined by assessing whether the neuro-muscular response is greater than a predetermined onset level and increasing the electrical stimulus until the determined neuro-muscular response is greater than the predetermined onset level; and the amplitude greater than the predetermined value comprises a peak-to-peak value greater than the predetermined value (the peak-to-peak value is nothing more than the overall action potential, since the action potential consists of a maximum peak and a minimum peak before returning to the resting potential). See pages 2780-2782.

Since both Neubardt and Calancie et al disclose means for monitoring stimulus evoked responses, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Neubardt to include the use of electrically monitoring the EMG response, as per the teachings of Calancie et al, since it would provide a more accurate means of monitoring the status of the pedicle screw in relation to the spinal nerve. It also would have been obvious to one of ordinary skill in the art to apply the monitoring means to the arms of the patient when working on the cervical spine.

Neubardt and Calancie et al however fail to disclose increasing the electrical stimulus in constant increments until a response is detected using a neurophysiology system; the use of an audible indicator for indicating an intensity level of the response;

sounding an alarm; varying the volume of the alarm; and varying the frequency of the alarm.

Raymond et al disclose a means of protecting nerves from injury during surgery, and further disclose increasing the electrical stimulus in constant increments until a response is detected using a neurophysiology system; the use of an audible indicator for indicating an intensity level of the response; sounding an alarm; varying the volume of the alarm; and varying the frequency of the alarm. See Column 7, lines 8-16; Column 8, lines 14-38; and Column 9, line 68-Column 10, line 4.

It would have been obvious to one of ordinary skill in the art to modify the combination of Neubardt, Calancie et al to include the use of constant electrical stimulus increments and an audible indicator, as per the teachings of Raymond et al, since it would provide an accurate means of detecting the onset neuromuscular response and an additional means of alerting the user above a visual stimulus.

Neubardt and Calancie et al and Raymond et al however fail to disclose automatically increasing the electrical stimulus until a neuromuscular response is detected; communicating to the surgeon includes visually displaying to the surgeon an intensity level representing the onset electrical stimulus level causing the onset neuromuscular response; and visually displaying involves the use of an integrated display.

Katims discloses an automated current perception threshold determination device and further discloses automatically increasing the electrical stimulus until a neuromuscular response is detected; communicating to the surgeon includes visually

displaying to the surgeon an intensity level representing the onset electrical stimulus level causing the onset neuromuscular response; and visually displaying involves the use of an integrated display. See Figure 2; Column 7, lines 19-32; and Column 34, lines 9-23.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to change the manual operation as disclosed by the combination of Neubardt, Calancie et al and Raymond et al, to an automatic operation, as taught by Katims, since the replacement of a manual operation with an automatic operation is a design consideration within the skill of the art. See In re Venner, 262 F.2d 91, 120 USPQ 192 (CCPA 1955).

8. Claims 2, 29 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558), Calancie et al (Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation), Raymond et al (5,284,153), and Katims (5,806,522) as applied to claims 1, 14 and 27 above, and further in view of Jacobson (4,545,374).

Neubardt, Calancie et al, Raymond et al and Katims, as discussed above, disclose a means for monitoring the onset neuromuscular response to an applied stimulus, but fail to disclose the electrical stimulus is delivered from an electrode disposed on the distal end of an instrument inserted through a cannula toward the bone.

Jacobson discloses a means for monitoring nerves during a percutaneous lateral diskectomy, and further disclose the electrical stimulus is delivered from an electrode

disposed on the distal end of an instrument inserted through a cannula toward the bone. See Column 6, lines 52-56.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Neubardt, Calancie et al, Raymond et al, and Katims to place the probe of Neubardt, with an electrode disposed on the distal end thereof, through a cannula to the bone in order to provide an electrical stimulus to provoke a neuromuscular response, as per the teachings of Jacobson, since it would provide a less invasive means of accessing the spine and testing the nerve response to the electrical stimulus.

9. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558), Calancie et al (Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation) and Katims (5,806,522) as applied to claim 14 above, and further in view of Epstein et al (6,259,945 B1).

Neubardt, Calancie et al and Katims, as discussed above, disclose a means of monitoring the muscle response of a stimulated nerve during spinal surgery, but fail to disclose visually displaying includes illuminating lights.

Epstein et al disclose a means for locating a nerve and further disclose the use of illuminating lights to convey the electrical stimulus current level that elicits an onset muscle response. See Column 5, lines 6-11.

Since Neubardt, Calancie et al and Katims disclose means for visually alerting a user to the EMG status, but fail to disclose colored lights representing the measured status, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify the combination of Neubardt, Calancie et al and Katims to include the use of illuminating lights for indicating the current level that elicits an onset response, as per the teachings of Epstein et al, since lights provide an alternative means of providing information to a user.

10. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558), Calancie et al (Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation) and Katims (5,806,522) as applied to claim 14 above, and further in view of Epstein et al (6,259,945 B1) in view of Chen et al (6,138,681).

Neubardt, Calancie et al and Katims, as discussed above, disclose a means of monitoring the muscle response of a stimulated nerve during spinal surgery, but fail to disclose displaying different lights on the display when the current value is below a predetermined level, and each light corresponds to a warning to the surgeon.

Epstein et al, as discussed above, disclose a means of using different lights to indicate the stimulus level and the lights provide a warning to the surgeon.

Since Neubardt, Calancie et al and Katims disclose means for visually alerting a user to the EMG status, but fail to disclose colored lights representing the measured status, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Neubardt, Calancie et al and Katims to include the use of different lights to indicate the stimulus level and provide a warning to the surgeon, as per the teachings of Epstein et al, since utilizing lights on a medical

monitor also provides an easily readable indicator to the surgeon performing the medical procedure.

Neubardt, Calancie et al, Katims and Epstein et al however fail to explicitly disclose the use of different colored lights on the device to indicate a signal value below a baseline.

Chen et al disclose a means for indicating the alignment of an external medical device to an internal medical device, and further disclose the use of different colored lights on the device to indicate a signal value below a baseline (the lights indicate a baseline; if the transmitter is close to the implanted device, a light will be illuminated; the closer the transmitter is to the implanted device, more lights will be illuminated). See Column 8, lines 5-11.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Neubardt, Calancie et al, Katims and Epstein et al, to include the use of colored lights to provide an indication of a signal below a baseline, as per the teachings of Chen et al, since it would provide a visual indication means that is easily interpreted by a user.

Response to Arguments

11. Applicant's arguments with respect to claims 1, 14 and 27 have been considered but are moot in view of the new ground(s) of rejection.

Even though the claims are rejected under a new grounds of rejection, the Examiner would like to respond to some of the Applicant's arguments to try to further

prosecution. With respect to the Applicant arguments pertaining to the combination of Neubardt, Calancie et al and Katims not disclosing visually displaying to the surgeon an electrical current value representing the onset electrical stimulus current level causing the onset neuromuscular response, the Examiner would like to respectfully point out Katims does disclose a display for displaying current perception threshold (CPT) data after the test is performed (Column 17, lines 58-60). The data for the CPT would obviously include the current level supplied to the patient to elicit the patient response. Furthermore, the Applicant argues Katims does not disclose the display showing the current stimulation value, And therefore fails to teach a display for displaying the current level that provokes the onset neuromuscular response. The Examiner respectfully disagrees. Display 100 in Katims is used to display instructions as well as CPT data, including a current stimulus level. A user, or optionally automatically performed, increases the stimulus level until the patient provides a response to the stimulus. Katims further discloses the operator monitors the stimulus intensity as indicated on the display 100. See Column 15, lines 59-61. Therefore, one of ordinary skill in the art, when viewing the combination of Neubardt, Calancie et al, (Raymond et al) and Katims, would be able to determine the display of Katims would provide the teachings for displaying an electrical current level that provokes the onset neuromuscular response, such that a user (or surgeon) can visually monitor the stimulus intensity simply by viewing the display.

With respect to the Applicant arguments pertaining to increasing the electrical stimulus in constant increments, the previously relied upon prior art of Raymond et al is

being utilized to teach the claimed limitation. Raymond et al teach the use of constant increments of an electrical stimulus to elicit a neuromuscular response, as noted above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736